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PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Nicholas R. Bachur, Jr. et al.

**EXPEDITED RESPONSE
UNDER RULE 116**

SERIAL NO.: 09/892,061

GROUP: 1744

FILING DATE: June 26, 2001

EXAMINER: W. Beisner

FOR: System and Method for Optically Monitoring the Concentration of a Gas, or the Pressure in a Sample Vial to Detect Sample Growth.

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July 23, 2004
(DATE OF DEPOSIT)

Nicole M. McRae
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(SIGNATURE)

7/23/04
(DATE)

AMENDMENT UNDER RULE 37 CFR § 1.116

Sir:

This paper is in response to the Official Action dated June 3, 2004.

Please consider **the Remarks/Arguments** beginning on Page 2 of this response.

REMARKS

Claims 1-62 are in the present application.

The Examiner has rejected Claims 1, 3, 4, 6, 8 – 10, 20, 22, 24, 26 – 29, 59 and 61 under 35 USC Section 103(a) as allegedly rendered unpatentable by Sussman et al in view of Wrobel et al. Claims 2, 7, 21 and 23 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Sussman et al in view of Wrobel et al and Fraatz et al. Claims 39-41 and 45-47 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Sussman et al in view of Wrobel et al and Carr et al. Claims 51, 52, 55 and 56 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Sussman et al in view of Berndt et al.

Claims 5, 11, 13, 15, 17, 18, 19, 25, 30, 32, 34, 36, 37, 38, 60 and 62 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Sussman et al in view of Wrobel et al and Waters and Brace. Claims 12, 14, 31 and 33 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Sussman et al in view of Wrobel et al, Waters, Brace and Fraatz et al. Claims 42 – 44 and 48 – 50 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Sussman et al in view of Wrobel et al, Waters, Brace and Carr et al. Claims 53, 54, 57 and 58 have been rejected under 35 USC Section 103(a) as allegedly rendered unpatentable by Sussman et al in view of Wrobel et al, Waters, Brace and Berndt et al.

None of the cited prior art teaches or suggests the claimed invention.

The present invention is directed to systems and methods for detecting the growth of microorganisms in a sample in a container by monitoring pressure or the concentration of a gas related to microorganism metabolism in the container.

Sussman, et al teach a method and apparatus for detecting CO₂, produced by metabolizing microorganisms, in a sealed bottle, and by the use of IR spectroscopy by shining a source of IR irradiation of the appropriate wavelengths, in the form of a wavelength scan, through the neck of the bottle. They use a scanning IR spectrometer to acquire the bottle scans (abstract; col 2, lines 48 – 53; Example 1-col. 6, lines 60 – 61; Figures 2 – 5). The IR source for this analysis is not a diode laser. Sussman et al also teach that the CO₂ is measured in the 2.3 – 2.4 micron wavelength region.

Wrobel et al teaches a tunable IR diode laser. The Examiner has alleged that if one were to combine the diode laser of Wrobel et al, with the method and apparatus of Sussman et al, one would achieve the instant invention. However, there are several things wrong with Wrobel et al that make it unusable for the instant invention:

1. Wrobel et al's diode laser needs to be cooled in liquid helium (Col 2., Lines 59-61). This makes it very impractical, and in fact, impossible for a commercial product or use in the microbiology laboratory.
2. Wrobel et al state that the diode laser taught is functional in the 2-6 micron range. The present invention claims the detection of certain gases that may be produced as products of microbial growth, such as O₂, CH₃, NH₃, H₂S which all fall outside of the range of Wrobel et al (for example, O₂ is at 0.7615 microns; NH₃ is at 1.997 microns; H₂S is at 1.570 microns; CH₄ is at 1.650 microns). Thus the Wrobel et al diode laser could not be used with Sussman et al to achieve the instant invention.
3. The Wrobel et al patent issued in 1974. If it would have been "obvious" to use Wrobel et al with Sussman et al, Sussman et al would have mentioned (some 20 years later) the use of lasers as an IR light source instead of just relying on "off the shelf" IR spectrometers (without a laser IR source). Applicants respectfully submit that Sussman et al did not mention Wrobel et al because of the commercial impracticality of cooling a laser with a liquid helium.

Any use of Fraatz et al as a 103 reference is also incorrect and improper since Fraatz uses a sensor inside the bottle and is based on a color change induced by CO₂ changing the pH of the sensor environment. It does not use IR spectroscopy from outside the bottle and read through the neck of the bottle. The instant invention has no sensor inside the bottle, and is based on IR absorbtion, not pH change.

Brace was discussed in the previous Amendment of March 8, 2004. Brace does not contain the elements of the claimed invention. Brace is specific only for the measurement of pressure, but by teaching a very specific method (see Col. 2, Lines 15 – 40) that is totally distinct from the claimed pressure method in the present application. Applicants teach a method involving the width of the absorption peak as a measurement of pressure, as temperature is held constant. (Page 17 of the

specification, paragraph [0065] and [0066]). In addition, Applicants use a laser, which emits light at a single wavelength, not a wavelength (or frequency) band, which is taught in Brace (see, for example, Col. 2, Line 2, 28). If the present invention used the method disclosed in Brace for pressure measurement, this might be an issue. But the present invention uses a totally different method.

Waters uses a deformable membrane to indicate the production of gas (pressure increase) as a consequence of metabolizing microorganisms. (see col. 2, lines 6 – 28). In other words, there is a physical change to the size, shape, or height, of the deformable membrane. The present invention uses changes to the absorption spectrum (see paragraph 68, for example).

The other secondary references, Carr et al and Berndt et al provide no further teachings which would enable one of ordinary skill in the art to achieve the claimed invention when in combination with the other cited references.

Accordingly, the claimed invention is neither taught nor suggested by the cited prior art references. Therefore, withdrawal of the present rejections under 35 USC Section 103 is respectfully requested.

Thus in view of the above remarks, it is believed that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "B.S. Weintraub", with a stylized flourish at the end.

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